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PATENT & TRADEMARK OFFICE

PATENT
Attorney Docket No.: 2785-1-00PCTCIP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: James Dobbie
Examiner: Kishore, Gollamudi

Serial No.: 10/678,743
Group Unit: 1612

Filed: October 3, 2003

For: COMPOSITIONS AND METHODS OF USING LAMELLAR BODIES FOR THERAPEUTIC PURPOSES

CERTIFICATE OF MAILING UNDER 37 CFR 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the COMMISSIONER FOR PATENTS, P.O. Box 1450, Alexandria, VA 22313-1450 on January 29, 2010.

Michele Hofherr
(Name of Depositor)

Michele Hofherr 1-29-10
(Signature and Date)

DECLARATION OF DUNCAN LAWRENCE UNDER 37 C.F.R. §1.132

I, Dr. Duncan Lawrence, hereby declare and state as follows:

1. I am the Managing Director of Lamellar Biomedical Limited, the assignee of the present application. I have over 20 years experience in the contract research industry developing novel medicines for pharmaceutical and biotechnology companies and the following experimental work was carried out under my instruction.

2. Surface tension of different lipid compositions has been used as an indicator of their anti-adhesive property. The surface tension of lipid compositions when formulated in saline (0.9% NaCl) buffer can be measured using a goniometer.

3. The lipid compositions LMS-171, LMS-261, LMS-351, LMS-611, LMS-524 and LMS 621 were prepared as described at paragraph [0147] of the present patent application.

4. Figure 1 and Table 1 provided in Appendix A report the surface tension of different lipid compositions. These data show the surface tension of the claimed composition to be significantly lower than that of other lipid compositions. In view of these results the claimed composition is predicted to be more effective in preventing adhesions.

5. Figure 2 provides an electron micrograph image of the claimed composition showing this takes the form of multi-lamellar vesicles.

6. The ratio of cholesterol in the composition has been found to be critical for activity. When the ratio of cholesterol is increased (eg to 36% as in LMS-621) or removed (eg to 0% as in LMS-542) the composition is not as effective in lowering surface tension. Cholesterol in the ratio 4-12% of the composition is considered to produce the optimum vesicle structure with the necessary flexibility, deformability and permeability for anti-adhesive activity.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

29 January 2010

Date

Duncan Lawrence

Appendix A

Figure 1: The surface tension of different lipid combinations formulated in 0.9% NaCl buffer.

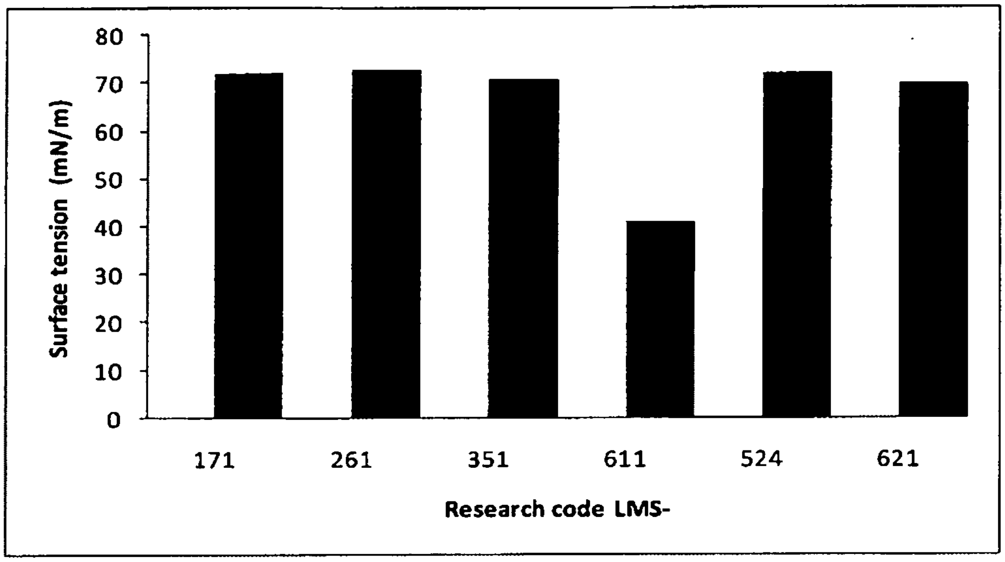

Figure 2: An electron micrograph of LMS-611 multi-lamellar vesicles.

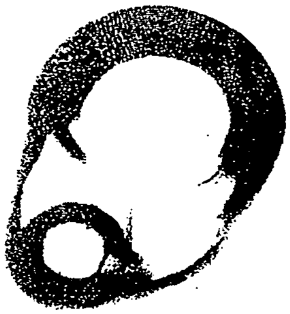

Table 1: The surface tension of different lipid combinations formulated in 0.9% NaCl buffer.

Research code	Lipid composition (%)						Surface tension (mN/m)
	PC	CH	SM	PE	PI	PS	
LMS-171	100						72
LMS-261	84	16					73
LMS-351	65	12	23				71
LMS-611	55	10	20	8	3	4	41
LMS-524	55		30	8	4	3	61
LMS-621	55	36	5	2	1	1	70

Key: PC – phosphatidylcholine; CH – cholesterol; SM – sphingomyelin; PE – phosphatidylethanolamine; PI – phosphatidylinositol; PS – phosphatidylserine.

CURRICULUM VITAE

DUNCAN JOHN LAWRENCE *MBA PhD*

EMPLOYMENT

2007 -	Lamellar Biomedical Ltd, Managing Director
2006 - 2006	Kendle International Ltd, Director, Regulatory Affairs Services
2004 - 2006	Charles River Laboratories Clinical Services, Executive Director, Regulatory Affairs Services
1997 - 2004	Inveresk Research, Director, Client and Regulatory Services (Clinical)
1995 – 1997	Quintiles, Director, Preclinical Business Development
1988 - 1994	Inveresk Clinical Research, Non-Executive Director, Commercial Operations
1987 – 1995	Inveresk Research International, Business Manager
1984 – 1987	Huntingdon Research Centre, Head of Biochemical & Behavioural Pharmacology

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EDUCATION

1981 – 1984	Postdoctoral fellow, University of Calgary, Canada
1989 – 1992	Masters in Business Administration, University of Edinburgh, UK
1978 – 1981	Doctor of Philosophy, University of Bristol, UK
1974 – 1978	Bachelor of Science, University of Glasgow, UK